

## **510(K) SUMMARY**

K070726

In accordance with 21 CFR 807.92

### **1. Date of preparation**

March, 8 2007

### **2. Company information**

MAY - 2 2007

BarcoView  
35 President Kennedypark  
B-8500 Kortrijk, Belgium  
Tel. +32-(0)56-233-211  
Fax +32-(0)56-233-457

### **3. Contact person**

Lieven De Wandel  
Official correspondent

### **4. Device information**

- Trade name: MDNC 3120
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

### **5. Predicate device**

- Name: E-2320C
- 510(k) number: K052958
- Manufacturer: Barco NV

### **6. Device description**

MDNC 3120 is a 20.8" color LCD display for medical viewing. It is combined with MediCal QAWeb Agent, a user-friendly software that allows to optimize the display for DICOM-compliant viewing.

### **7. Intended use**

"The MDNC 3120 is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography. The MDNC 3120, which is part of the Nio Color 3MP system, will be marketed separately.

### **8. Summary of technological characteristics**

The flat panel display has a resolution of 2048 x 1536 pixels. It can be used in landscape or portrait mode.

The MediCal QAWeb Agent software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, the MDNC 3120 display has a different LCD panel, other electronic and mechanical parts. The basic specifications and functions, however, are the same.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

## **9. Conclusion:**

The Barco MDNC 3120 is substantially equivalent to the predicate device, E-2320C.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco MDNC 3120 contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

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### **3. Contact person**

Lieven De Wandel

Official correspondent

### **4. Device information**

- Trade name: Nio Color 3MP
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

### **5. Predicate device**

- Name: Color Nio 2MP
- 510(k) number: K052958
- Manufacturer: Barco NV

### **6. Device description**

Nio Color 3MP is a display system for medical viewing. It consists of 3 components:

MDNC 3120 is a 20.8" color LCD display. MediCal QAWeb Agent is a softcopy QA software application for local calibration and QA control. The system also contains a fast high-resolution display controller board that plugs into a PACS workstation computer. Standard the system is delivered with the MXRT 2100 board, but the user can opt for another type of display controller board (MXRT 5100 or MXRT 7100)

The display system can be a single-head system or multi-head system. In the last case it contains multiple displays and display controller boards.

### **7. Intended use**

"The Nio Color 3MP is intended to be used in displaying and viewing digital images for review by

trained medical practitioners. These devices must not be used in primary image diagnosis in mammography. The Nio Color 3MP, containing the display MDNC 3120, the software MediCal QAWeb Agent and a graphic board, will be marketed as separate device.

## **8. Summary of technological characteristics**

The device consists of three components:

- One 3-megapixel flat panel display (MDNC 3120)
- One 32-bit display controller
- MediCal QAWeb Agent software

The flat panel display has a resolution of 2048 x 1536 pixels. It can be used in landscape and portrait mode.

The display controller board is an ultra-high speed board with a 32-bit in, 32-bit out lookup table, providing up to 64 bit color.

The MediCal QAWeb Agent software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, the display from the Nio Color 3MP system has a different LCD panel, other electronic boards and other mechanical parts. The software is a new version. However, the basic specifications and functions of all the parts are the same.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

## **9. Conclusion:**

The Barco Nio Color 3MP is substantially equivalent to the predicate device, Color Nio 2MP. The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco Nio Color 3MP contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Mr. Lieven De Wandel  
Official Correspondent  
BarcoView Medical Imaging Systems  
President Kennedypark 35  
B-8500 Kortrijk  
BELGIUM

MAY - 2 2007

Re: K070726

Trade/Device Name: Nio Color 3MP and MDNC 3120

Regulation Number: 21 CFR §892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: March 8, 2007

Received: March 15, 2007

Dear Mr. De Wandel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address  
<http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K070726

Device Name: Nio Color 3MP

### Indications for Use:

"The Nio Color 3MP is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography. The Nio Color 3MP, containing the display MDNC 3120, the software MediCal QAWeb Agent and a graphic board, will be marketed as separate device.

Prescription Use XX

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K070726

## INDICATIONS FOR USE

510(k) Number (if known): K070726

Device Name: MDNC 3120

### Indications for Use:

"The MDNC 3120 is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography. The MDNC 3120, which is part of the Nio Color 3MP system, will be marketed separately.

Prescription Use XX

(Part 21 CFR 801 Subpart D) AND/OR  
(21 CFR 801 Subpart C)

Over-The-Counter Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Nancy Crogdon*  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Endocrinological Devices  
510(k) Number K070726